

Patient Guide for Cynril[®] Lozenges (fentanyl citrate lozenges)



You have been prescribed Cynril® (fentanyl citrate) lozenges for your breakthrough cancer pain (BTcP)

Important notice;

Do not use Cynril unless you have been regularly using other opioid medicines for your persistent cancer pain for at least a week.

- **Do not give Cynril to anyone else**, even if they appear to have the same symptoms as you.
- **Keep all units of Cynril in a safe and secure location**, away from other people. Keep out of reach and sight of children. If a child or anyone else has accidentally taken an opioid medicine, **call for emergency medical assistance immediately** as it may be life-threatening.
- **Cynril should only be used for BTcP.**
- **Do not use Cynril if you are below the age of 16.**

Before you start taking Cynril® and every time you get a new prescription (as it may contain new information) please **read the patient information leaflet that is found with the Cynril®** treatment. Share the information with members of your household. If you have concerns regarding Cynril® or any other treatment you are receiving please consult your doctor.

The doctor will have prescribed a starting dose of Cynril®, do not substitute Cynril® for another fentanyl medicine to treat BTcP without discussing with your doctor.

Precautions you should take into consideration before using Cynril®

- Cynril® can have life-threatening effects particularly, breathing problems:
 - if you do not use Cynril® the way it has been described by your doctor
 - if you are not regularly using other opioid medicines for your persistent cancer pain
- Cynril is a medication for BTcP, do not use for any other pain or short term pain such as for injuries, surgery, headaches, migraines or any other type of pain aside from BTcP.
- As each Cynril® lozenge contains 2 grams of sugar, you need to maintain regular oral hygiene by:
 - Brushing your teeth twice a day
 - Flossing daily
 - After each Cynril® application, rinse mouth with water or brush teeth.
 - See the dentist twice a year to maintain dental hygiene.
 - Only use Cynril® if you are taking opioid pain medication every day on a regular schedule for at least a week, for controlling your persistent pain. Do not stop taking your opioid persistent treatment while taking Cynril® without discussing this with your doctor.
 - Cynril® should not be used to treat any other pain aside from BTcP.
 - Please do not hesitate to speak to your doctor should you have any questions concerning your treatment.
 - Your doctor will use a process called **titration** to find an appropriate dose that will be effective in relieving your BTcP with minimal side effects. this dose is your maintenance dose.

Please read the patient information leaflet for complete information regarding Cynril®.

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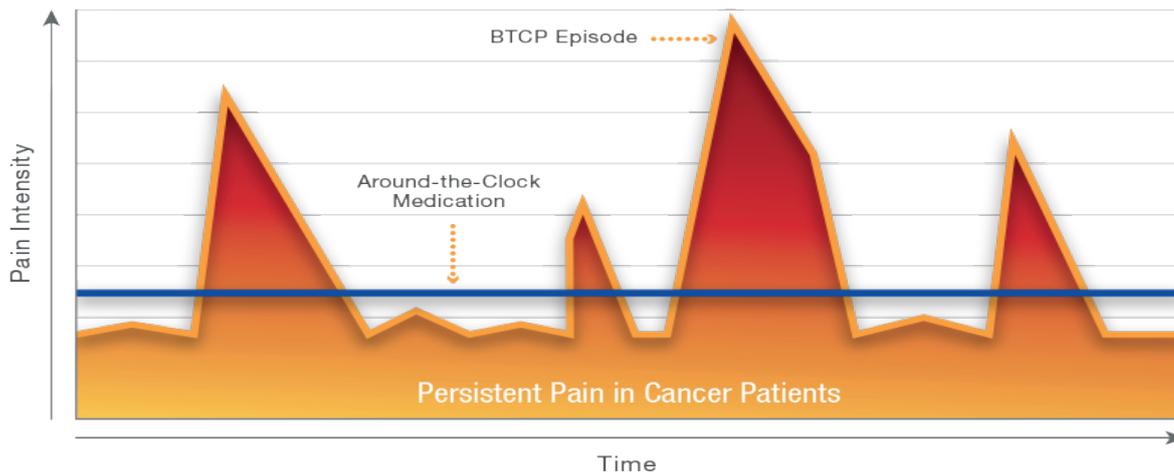
1. Breakthrough Cancer pain

1.1 What is Breakthrough cancer pain (BTcP)?

The degree of cancer pain can vary from mild to severe and can last throughout the day, this is called persistent cancer pain. This is usually controlled by taking medication- your doctor will have given you an opioid medicine that will relieve this pain for the whole day.

Although you are on prescribed opioid medicine you may still experience sudden flares of sharp stabbing, aching or radiating pain, this is breakthrough cancer pain (BTcP).

Illustration of Persistent Pain and Breakthrough Cancer Pain¹



Characteristics of BTcP

- BTcP varies from patient to patient.
- It can be moderate to severe.
- Maybe predictable or unpredictable- the breakthrough pain may be triggered by an activity.
- It may interfere with mood, sleep and other daily activities.

2. Cynril®

2.1 What is Cynril®?

Cynril® belongs to a class of drugs called opioids, it is a pain relieving medicine, indicated for BTcP in adults who are already taking opioid pain relief for their persistent cancer pain. Cynril® is a prescription only medicine. It contains the active ingredient fentanyl citrate.

2.2 How does Cynril® work?

The Cynril® lozenge will need to be placed in between the inner cheek and the gum, this is where the lozenge will dissolve. The active ingredient Fentanyl will be absorbed from the lining of the mouth to the blood circulation and subsequently, throughout the body. Fentanyl citrate will travel to the brain and the spinal cord which is collectively known as the central nervous system. This is where it will work to relieve the BTcP.

2.3 How does Cynril® differ from the medicine you take for persistent pain?

The opioid medicine you already take works all throughout the day, Cynril® however, is a treatment for BTcP only the sharp intense flares of pain. You must continue to take your opioid treatment for persistent pain while using Cynril®.

2.4 When should you use Cynril®?

Once your doctor has determined that Cynril® is an appropriate treatment for you, you should take Cynril® as soon as you start to feel an episode of BTcP. You should only use Cynril® if you are using other opioid pain medicine daily.

2.5 What does Cynril® taste like?

Cynril® contains artificial berry flavour

2.6 Is there sugar in Cynril®?

Yes, Cynril® contains 2 grams of sugar. It is important to maintain oral hygiene by

- Brushing your teeth twice a day
- Flossing daily
- After each Cynril® application, rinse mouth with water or brush your teeth.
- See the dentist twice a year to maintain dental hygiene.

2.7 How is Cynril® Packaged?

Cynril® is packaged in individual blister packages.

Important notices before starting Cynril® treatment:

Please remember

- Only use Cynril if you have been experiencing BTcP.
- Never use Cynril for any other pain except BTcP.
- Only use Cynril if you are using other opioid medicine daily.
- Do not stop your opioid treatment for persistent pain while you are taking Cynril without consulting your doctor.
- Under no circumstances should you give your medication to anyone else, even if it appears they have the same symptoms as you.
- Use Cynril exactly how your doctor/pharmacist has shown you.

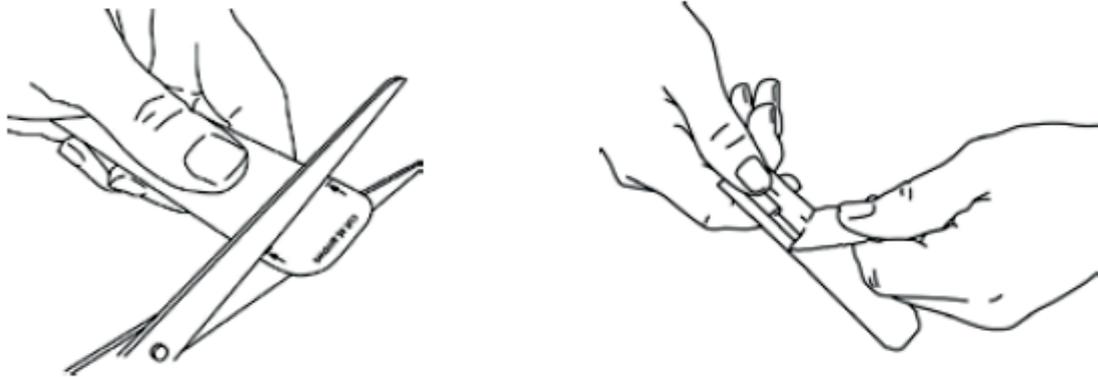
3. Using Cynril®

3.1 How do you take Cynril®?

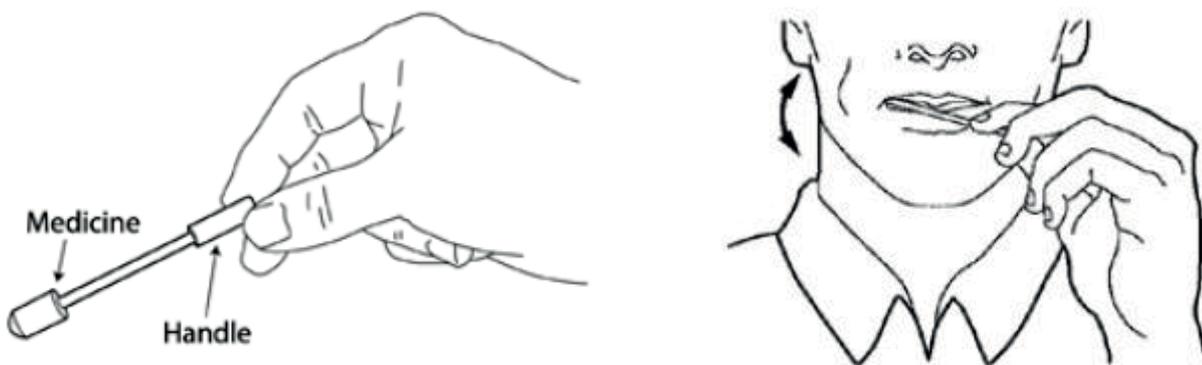
- You should not eat or drink anything while using Cynril®
- You may drink water **before** using Cynril®
- Do not open blister package until you are ready to use Cynril®

Opening the package;

- Each Cynril® unit is packaged in its own blister package
- Hold the blister package with the printed side away from you
- **Do not push** the lozenge through the blister pack
- Hold the short tab end of the blister package
- Put the scissors close to the end of the Cynril® unit and cut the long tab end completely off as shown.
- Separate the printed backing from the blister package and pull the printed backing completely off from the blister package.



Remove the Cynril® unit from the blister package and put the lozenge in your mouth straight away.



- Put the lozenge between your cheeks and gum.
- Using the handle, keep moving Cynril® around your mouth especially along your cheeks.
- Twirl the handle often.
- To get the most effective relief, finish the Cynril® completely in 15 minutes. If you finish too quickly, you will swallow more of the medicine and get less relief from your breakthrough pain.
- Do not bite or chew the lozenge. This would mean lower levels of fentanyl in your blood and less pain relief than when used as directed.
- If for some reason you are not finishing the whole lozenge each time you have breakthrough pain, talk to your doctor.

Important:

Use as directed by your doctor;

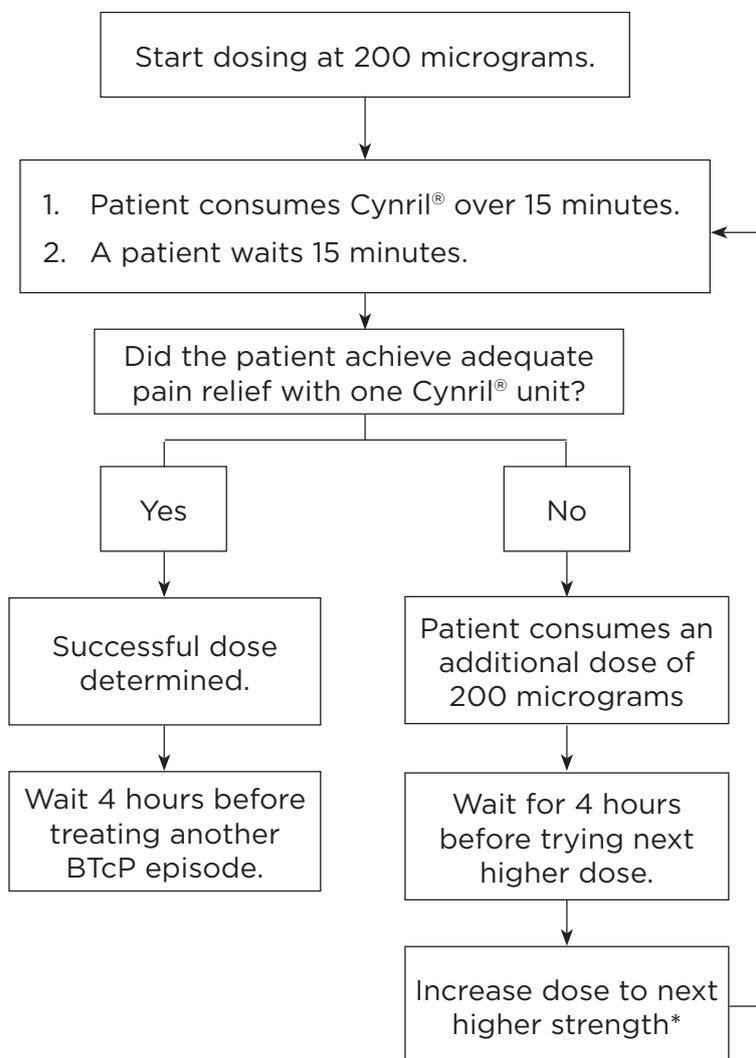
- Understand the correct way to use Cynril® by reading instructions on patient information leaflet and this patient guide-consult your doctor or pharmacist if you want more information.
- To protect the lozenges, open blister packages only when you are ready to take Cynril®. Do not store them in pill boxes.

3.2 How does the doctor determine the dose suitable for you?

Cynril® is available in multiple dosages strengths, your doctor will use a process called titration to find the appropriate dose for you that will be effective in relieving your BTcP with minimal side effects.

Titration process:

1. Take Cynril® over 15 minutes
2. **Wait 15 more minutes**
3. If the pain is not relieved sufficiently take **ONLY ONE** additional lozenge over 15 minutes.
4. Take no more than 2 units per BTcP episode
5. Wait a minimum of 4 hours before treating another episode of BTcP with Cynril®



*Dose concentrations available are 200, 400, 600, 800, 1200 and 1600 micrograms.

Do not use more than 1 units of Cynril® strength that have been determined for you, to treat any single episode of breakthrough pain. Do not have more than 4 units per day.

During the dose adjustment period tell your doctor how you are feeling, as that will help determine the dose suitable for you.

Keeping a treatment diary will be useful to note your experiences, you can then discuss these experiences with your doctor. Ask your doctor for more details.

3.3 What if you still experience pain after a single dose of Cynril® even after your correct dose has been determined?

If the dose determined by your doctor does not relieve your breakthrough pain **contact your doctor**. They will decide if your dose needs to be changed.

3.4 When can you treat another BTcP episode with Cynril®?

Please follow the instructions that were given to you by your doctor or pharmacist on how often Cynril® should be taken. Wait at least 4 hours before treating another BTcP episode. If you are regularly experiencing more than 4 BTcP a day, consult your doctor.

3.5 Can you bite, chew or swallow Cynril®?

No, do not bite chew or swallow the whole Cynril® lozenge.

3.6 What happens if you swallow Cynril®?

if swallowed before Cynril® lozenge has crossed the lining of your mouth, you may experience less relief for your breakthrough pain.

3.7 Can Cynril be taken if you have dry mouth (xerostomia)?

Yes, you can, the lozenge may take longer to dissolve. Water can be used to moisten the oral cavity **before** using Cynril® lozenge.

3.8 While taking Cynril® should you continue using my opioid treatment for persistent pain?

You MUST take your opioid medicine for persistent cancer pain while taking your Cynril® medication. **DO NOT** stop using your opioid treatment given to you for your persistent pain without speaking to your doctor.

Important Notices.

- Use Cynril® the way it has been described by your doctor.
- Wait a minimum of 30 minutes before taking an additional dose of Cynril® for an unrelieved BTcP episode during the dose adjustment phase.
- Wait at least 4 hours before taking a Cynril® for another BTcP episode.
- If you regularly experience more than 4 BTcP episodes a day, please contact your doctor.

4. Potential side effects of Cynril®

4.1 Potential side effects/likely side effects

The most serious side effects are shallow breathing, low blood pressure and shock.

You or your caregiver should REMOVE the Cynril® unit from your mouth, contact your doctor immediately and call for emergency help if you experience any of the following serious effects - you may need urgent medical attention:

- Becoming very sleepy or having slow and/or shallow breathing.
- Difficulty in breathing or swelling of the tongue, lip or throat, which may be early signs of serious allergic reaction.

Note to carers:

If you see that the patient taking Cynril® has slow breathing or if you have a hard time waking the person up, take the following steps IMMEDIATELY:

- Using the handle, remove the Cynril® unit from the person's mouth and keep it out of reach of children or pets until the Cynril® unit is disposed of.
- CALL FOR EMERGENCY HELP.

If you are feeling dizzy excessively, sleepy or otherwise ill while taking Cynril®, use the handle to remove the Cynril® unit and dispose of it according to the instructions given in the patient information leaflet (this comes with the Cynril®). Contact your doctor for further directions on using Cynril®.

Very common side effects (may affect more than 1 in 10 people):

- Vomiting, nausea/discomfort, constipation, stomach (abdominal) pain.
- Asthenia (weakness), sleepiness, dizziness, headache.
- Shortness of breath.

Common side effects (may affect up to 1 in 10 people):

- Confusion, anxiety, seeing or hearing things that are not there (hallucinations), depression, mood swings.
- Feeling unwell.
- Muscle jerks, feeling of dizziness or "spinning", loss of consciousness, sedation, tingling or numbness, difficulty coordinating movements, increased or altered sensitivity to touch, convulsions (fits).
- Dry mouth, mouth inflammation, tongue problems (e.g. burning sensation or ulcers), taste alteration.
- Wind, abdominal bloating, indigestion, decreased appetite, weight loss.
- Blurred or double vision.
- Sweating, skin rash, itchy skin.
- Difficulty passing urine.
- Accidental injury (e.g. falls).

Uncommon side effects (may affect up to 1 in 100 people):

- Tooth decay, paralysis of the gut, (which may cause side effects such as stomach cramps, being sick, loss of bowel movements and being unable to pass wind), mouth ulcers, gum bleeding.
- Coma, slurred speech.
- Abnormal dreams, feeling detached, abnormal thinking, excessive feeling of wellbeing.
- Widening of blood vessels.
- Hives.

Not known (frequency cannot be estimated from the available data):

They have also reported the following side effects with the use of Cynril® but how often that can occur is not known:

- Receding gums, swollen gums, tooth loss, severe breathing problems, flushing, feeling very warm, diarrhoea, swelling of arms or legs, fatigue, insomnia, pyrexia, withdrawal syndrome (may manifest by the occurrence of the following side effects nausea, vomiting, diarrhoea, anxiety, chills, tremor and sweating).
- Drug dependence (addiction).
- Drug abuse.
- Lack of sex hormones (androgen deficiency).

Prolonged treatment with fentanyl during pregnancy may cause withdrawal symptoms in the new-born which can be life-threatening (see section 2 of patient information leaflet).

While using Cynril® you may experience irritation, pain and ulcers in the application site and gum bleeding.

For more information on Cynril® and potential side effects please see the patient information leaflet that comes with your Cynril®. If you notice any side effects when taking Cynril® contact your doctor.

4.2 What to do if you have any of the symptoms mentioned.

Call your doctor and get emergency medical help right away if you experience the following:

- Becoming very sleepy or having slow and/or shallow breathing.
- Difficulty in breathing or swelling of the tongue, lip or throat, which may be early signs of serious allergic reaction.
- Extreme drowsiness with slowed breathing.
- Feeling faint, very dizzy, confused or have unusual symptoms.

These symptoms may lead to serious problems or death if not treated immediately.

The symptoms mentioned above may indicate that you have overdosed (taken too much Cynril®) or that you have taken a dose higher than you should.

If you feel very dizzy or very sleepy before the lozenge has completely dissolved, then immediately rinse your mouth and spit out remaining pieces of the lozenge into the sink or toilet.

Remember:

Call for medical help:

The most serious side effects are shallow breathing, low blood pressure and shock. If you have trouble breathing, feel faint, very dizzy, confused or have unusual symptoms then;

- Immediately spit out the remaining lozenge
- DO NOT take another Cynril®
- Call your doctor and get emergency medical help immediately

5. Interactions with Cynril®

5.1 The use of other medicines with Cynril®

Before starting Cynril®, ensure you have told your pharmacist or doctor about any medication you are taking or recently taken. This includes medicines obtained without prescription, vitamins or herbal supplements and any of the following medications;

- Any medicines which might make you sleepy such as sleeping pills, medicines to treat anxiety, some medicines for allergic reaction (antihistamines), or tranquillisers.
- Some muscle relaxants (such as baclofen or diazepam).
- Any medicines or other substances that might have an effect on the way in which your body breaks down Cynril®, such as: grapefruit juice, drugs used to treat fungal infections, ritonavir or other medications that help control the HIV virus (AIDS) or other medicines called “CYP3A4 inhibitors” such as ketoconazole, itraconazole or fluconazole (used for fungal infections) and troleandomycin, clarithromycin or erythromycin (medicines for bacterial infections) and so-called “CYP3A4 inducers” as rifampin or rifabutin for bacterial infections, carbamazepine, phenobarbital or phenytoin (medicines used to treat convulsions/fits).
- Certain types of strong painkillers, called partial agonist/antagonists e.g. buprenorphine, nalbuphine and pentazocine (medicines for the treatment of pain). You could experience symptoms of withdrawal syndrome (nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating) while using these medicines.
- Serotonergic medicinal products used to treat depression (antidepressants: such as selective serotonin reuptake inhibitors [SSRIs] and serotonin norepinephrine reuptake inhibitors [SNRIs]) or antipsychotics. The use of these medicines with Cynril® can lead to serotonin syndrome a potentially life-threatening condition (see section 2 under Serotonin syndrome). The symptoms of serotonin syndrome may include mental status changes (e.g. agitation, hallucinations, coma), and other effects such as body temperature above 38 °C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/ or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea). Your doctor will tell you whether Cynril® is suitable for you.
- Concomitant use of Cynril® and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However, if your doctor does prescribe Cynril® together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all the sedative medicines you are taking and follow your doctor’s dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

5.2 Cynril® with food, drink and alcohol

- Cynril® can be used before or after meals. However, do not use during a meal.
- You may drink some water before using Cynril® to moisten the mouth. However, you should not drink or eat anything while using Cynril®.
- Do not drink grapefruit juice while using Cynril®. This is because it may affect the way your body breaks down Cynril®.
- Do not drink alcohol while on treatment with Cynril®. It can increase the chance of getting serious side effects.

6. Storage, safe use and disposal information for Cynril®

6.1 The information you need to know before starting Cynril®

Do not use Cynril®:

- If you are not regularly using a prescribed opioid medicine (e.g. codeine, fentanyl, hydromorphone, morphine, oxycodone, pethidine), every day on a regular schedule, for at least a week, to control your persistent pain. If you have not been using these medicines you must not use Cynril®, because it may increase the risk of your breathing becoming dangerously slow and/or shallow, or even stop.
- If you are allergic to fentanyl or any of the other ingredients of this medicine (listed on section 6 of patient information leaflet).
- If you are currently taking monoamine-oxidase (inhibitor (MAOI) medicines for severe depression) or have taken them in the past 2 weeks (see section 2 under serotonin syndrome of patient information leaflet).
- If you have severe breathing problems or severe lung problems where you have an obstruction such as chronic bronchitis.
- If you suffer from short-term pain (e.g. pain from injuries, surgery, headaches or migraines) other than breakthrough pain.

Do not use Cynril® if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Cynril®.

Take special care with Cynril® if you have any of the following. Talk to your doctor or pharmacist before starting Cynril®

- Your other opioid pain medicine for your persistent (around-the-clock) cancer pain is not stabilised yet.
- You have an illness that affects your breathing (such as asthma, wheezing, or shortness of breath).
- You have a head injury or have had any loss of consciousness.
- You have problems with your heart, especially a slow heart rate.
- You have liver or kidney problems - this will affect how your system breaks down the medicine.
- You have low blood pressure due to a low amount of fluid in your circulation.
- You have diabetes.
- You are over 65 years old - you may need a lower dose and any dose increase will be reviewed very carefully by your doctor.
- You have a history of alcoholism or any drug abuse or dependence.
- You have ever developed adrenal insufficiency with opioid use, a condition in which the adrenal glands do not produce enough hormones (see section 4 under serious side effects).
- You drink alcohol; please refer to section Cynril® with food and drink and alcohol.
- You experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine as prescribed by your doctor.
- You experience a combination of the following symptoms: nausea, vomiting, anorexia, fatigue, weakness, dizziness and low blood pressure. Together these symptoms may be a sign of a potentially life-threatening condition called adrenal insufficiency, a condition in which the adrenal glands do not produce enough hormones.
- You have ever developed adrenal insufficiency or lack of sex hormones (androgen deficiency) with opioid use.

6.2 Driving and using machines

This medicine may affect you being able to drive or use any tools or machines. Talk to your doctor about whether it is safe for you to drive or use any tools or machines in the first few hours after using Cynril®. It is important that you know how to react to Cynril® before driving or operating machinery. **Do not drive or operate machinery if you are feeling sleepy or dizzy, have blurred vision, double vision or have difficulty in concentrating.**

6.3 Breastfeeding

Do not use Cynril® if you are breastfeeding. You should not start breastfeeding until at least 5 days after the last dose of Cynril®.

6.4 What to do if someone else accidentally takes Cynril®

If someone has accidentally consumed Cynril®. Seek medical help immediately. Try to keep the person awake (by calling their name and shaking their arm or shoulder) until the medical help arrives. They may have the same side effects as described in section 4.

6.5 What to do if you take more Cynril® than you should

The most common side effects of using too much Cynril® are feeling sleepy, sick or dizzy.

If you begin to feel dizzy, sick, or very sleepy before the lozenge is completely dissolved, take the lozenge out and rinse your mouth and call another person in your house to help you.

A serious side effect of Cynril® is slow and/or shallow breathing. This can occur if your dose of Cynril® is too high or if you take too much Cynril®. Other serious side effects associated with overdose include altered mental status, loss of consciousness, coma and cardiorespiratory arrest (sudden heart attack).

If this happens, get medical help straight away.

6.6 What to do if you forget to take Cynril®

If you still have breakthrough pain, you may use Cynril® as your doctor has told you. If the breakthrough pain stops, do not use Cynril® until the next breakthrough pain.

6.7 How to store Cynril®

The pain-relieving medicine in Cynril® is very strong and could be life-threatening if taken accidentally by a child. Cynril® must be kept out of sight and reach of children.

- Store Cynril® in original packaging to protect it from moisture.
- Do not use Cynril® after the expiry date shown on the package label and the carton.
- Do not store above 25°C.
- Always keep Cynril® in its blister package until you are ready to use it. Do not use if the blister package has been damaged or opened before you are ready to use it.

6.8 What to do if you no longer need to take Cynril®

Do not continue Cynril® if you no longer require it. Do continue to take your opioid medication to treat persistent pain and you can confirm the correct dose with your doctor. Please speak to your doctor or pharmacist if you have any further questions or would like more information.

6.9 How to dispense unopened Cynril® lozenges when you no longer need them

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Important notices

- Keep Cynril® in a secure and safe location whilst in and outside your home to prevent it from being stolen.
- Tell your doctor all medical and mental health problems including any drug or alcohol abuse, personal addiction problem and family history of these problems mentioned.
- Keep Cynril® out of sight and reach of children.
- If someone has accidentally consumed Cynril®. Seek medical help immediately. Try to keep the person awake (by calling their name and shaking their arm or shoulder) until the medical help arrives.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

7. Important considerations

- **Continue using your opioid medication for persistent pain every day while using Cynril®. You cannot take Cynril® if you are not using other opioid pain medication for persistent pain regularly.**
- **Only use Cynril® for BTcP-** do not use it to treat short term pain such as pain from injuries, surgery, headaches, migraines or any other type of pain aside from BTcP.
- **Use Cynril® as prescribed by your doctor.** Wait at least 4 hours before treating another BTcP episode, if you are regularly experiencing more than 4 episodes per day, speak to your doctor.
- **To prevent theft and misuse of Cynril®** keep it in a safe and secure location.
- **Keep Cynril® out of sight and reach of children.** Place it in a secure and safe location away from anyone else whom it has not been prescribed for.

If someone accidentally takes Cynril®:

Call for emergency medical help immediately

See patient information leaflet that comes with the Cynril® medication for more information. Contact your doctor if you have questions about the patient information leaflet or patient guide.

8. Additional information

8.1 Reporting side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: **www.mhra.gov.uk/yellowcard**. By reporting side effects you can help provide more information on the safety of this medicine.

Further information

For further information regarding your Cynril treatment and prescription please contact your doctor or pharmacist.

For additional copies of this guide or Cynril treatment diary, visit the Fontus health website at **www.fontushealth.com** or contact Fontus health limited medical information department on: Telephone number: **0121 661 4615** Email: **medinfo.uk@fontushealth.com**